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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/370,453	08/09/1999	DAN W. DENNEY JR.	GENITOPE-038	8128

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[REDACTED] EXAMINER

YAEN, CHRISTOPHER H

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1642

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/370,453	DENNEY, DAN W.
	Examiner Christopher H Yaen	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 January 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3-6 and 21-32 is/are pending in the application.

4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,3-6 and 25-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

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DETAILED ACTION

1. The amendment filed 1/6/2003 (paper no 18) is acknowledged and entered into the record. Accordingly, no claims have been added or canceled.
2. Currently, claims 1,3-6, and 21-30 are pending, claims 21-24 are withdrawn from further consideration as being drawn to a non-elected elected invention. Applicant is reminded to cancel all non-elected claims.
31-32 still pending (cy)
3. Therefore claims 1,3-6, 25-~~30~~ are examined on the record.

Objection Withdrawn

4. Upon further reconsideration, the objection to the specification under 35 USC 132 because it introduces new matter is withdrawn in view of the arguments presented by the applicant.

Claim Rejections Maintained- 35 USC § 112,1st paragraph

5. The rejection of claims 1,3-6, and 25-30 under 35 USC 112,1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instant specification does in fact enable the multivalent vaccine and further argues that the specification provides ample guidance towards the creation of a multivalent vaccine. Applicant's arguments have been carefully considered but are not found persuasive because the specification has not adequately taught one of skill in the art that a vaccine can in fact be made. As stated in the prior office action, the instant specification has enabled a multivalent composition comprising at least two recombinantly produced variable regions of an immunoglobulin derived from a B-cell lymphoma, however, the specification has not taught a vaccine comprising

recombinantly produced variable regions of an immunoglobulin. The specification has not provided any working examples or data to suggest to one of skill that the composition being claimed functions as a vaccine because the specification has not presented any challenge studies using the instantly claimed multivalent composition. Such studies would teach that following initial vaccination with the multivalent composition, any subsequent challenge with B-cell lymphomas cells would generate an immune response against the said lymphoma thereby preventing the re-occurrence of cancer. The instant specification has not provided any teach in this regard to demonstrate to one of skill in the art that the applicant was enabled for a vaccine. The composition claimed has only provided immediate treatment and has not been shown to be effective in a prophylactic regime. As such, the composition has only been taught as a medicament and not a prophylactic or therapeutic vaccine.

Claim Rejections Maintained- 35 USC § 103

6. The rejection of claims 1, 3-6, and 25-30 under 35 USC 103(a) as being obvious over Tao *et al*, Stevenson *et al*, and de The *et al* is maintained for the reasons of record. Applicant argues that there is no motivation to combine the references because none of the references disclose or teach of multivalency and multiple idotypic determinants. Applicant's arguments have been carefully considered but are not found persuasive. The claims are drawn to a multivalent vaccine composition, wherein the composition differs in idotypic determinants. The Tao *et al* reference teaches a fusion of cytokine and antibody derived from a B-cell lymphoma and it would have been obvious to combine with that of Stevenson *et al* because the antibody taught by Stevenson *et al*

has a different idotypic determinant than that of Tao *et al.* de The *et al* provides further motivation to make multivalent composition from B-cell lymphomas because de The *et al* describes the nature of Burkett's Lymphoma, a type of B-cell disease, and describes the polyclonal nature of B-cells. One of ordinary skill in the art would have found it obvious to combine the references because the instant invention has not provided any unexpected results that would have been obvious over the combination of several idotypic determinants. The de The reference only provides further motivation to combine because it teaches that a type of B-cell lymphoma has a tendency to display a polyclonal nature and that the construction of a composition that is multivalent and displayed multiple idotypic determinants would be more effective in combating lymphoma.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
April 3, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600